IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

LIFEWATCH SERVICES, INC., and CARD GUARD SCIENTIFIC SURVIVAL, LTD. *Plaintiffs,* v. BRAEMAR, INC., and ECARDIO DIAGNOSTICS, LLC *Defendants.*	Case No. 09-CV-6001 Honorable William J. Hibbler, U.S.D.J. Honorable Arlander Keys, U.S.M.J. **DEFENDANTS' RESPONSE TO PLAINTIFF'S LOCAL RULE 56.1 STATEMENT OF ADDITIONAL FACTS**

Pursuant to Local Rule 56.1, Defendants Braemar, Inc. ("Braemar") and eCardio Diagnostics, LLC ("eCardio") responds to LifeWatch Services, Inc.'s ("LifeWatch") Rule 56.1 statement as follows:

LifeWatch's '143 Patent

1. The '143 Patent, titled "Electrocardiographic Monitoring and Recording Device," was invented by Dr. Robert Schwarzberg. (Oczek Decl., Ex. A, cover page.)

Response: Defendants do not dispute this paragraph.

2. The patent application was filed with the U.S. Patent Office on May 3, 1996, and the '143 Patent was awarded on March 24, 1998. *(Id.)*

Response: Defendants do not dispute this paragraph.

3. LifeWatch is owner of all right, title, and interest in and to the '143 Patent. (Amended Complaint, Docket No. 75.)

Response: Defendants do not dispute this paragraph.

4. The invention of the '143 Patent relates to portable, wearable devices for recording and transmitting electrocardiographic (ECG) data. (Oczek Decl., Ex. A, col. 1, 11. 4-5; *see also* col. 2,11. 52-54.) The invention allows for real time evaluation of incoming ECG data in an "evaluation buffer" for the occurrence of a clinically significant event, such as a potentially life threatening cardiac arrhythmia. *(Id.,* col. 2, 11. 13-26.) The parameters of what constitutes a clinically significant event are adjustable and may be remotely programmable in accordance with the physicians' orders based upon the patient's medical history. *(Id.,* col. 2, 11.19-22.) Upon the occurrence of an event meeting the programmed parameters of the device, data stored in an evaluation buffer is transferred to a "holding buffer" and a patient alert can be triggered. *(Id.,* col. 2, 11. 22-26.) The patient can also manually trigger the transfer of data to the holding buffer. *(Id.,* col. 2, 11. 26-28.) The monitor device of the invention also includes a long-term memory for storing data for an extended period, before and/or after the trigger event. *(Id.,* col. 2, 11. 31-34.) The "long-term memory may be either solid state memory" *(e.g.,* FLASH memory) or "a magnetic tape or disk, etc. recorder." *(Id.,* col. 3, 11. 3 and 19-20.)

Response: Defendants object to this paragraph as violating Rule 56.1 in that it contains multiple statements of facts rather than a "short paragraph." Without waiving that objection, defendants provide the following response:

a. In response to the statement that starts with "Upon the occurrence of an event meeting the programmed . . .", defendants dispute that sentence and state that the '143 Patent provides "Upon the occurrence of an event meeting the programmed parameters, the data stored in the evaluation buffer (which can cover a period of time both before and after the event) is transferred to a holding buffer and a patient alert can be triggered." (Col. 2, lines 22-26).

b. In response to the statement "The monitor device of the invention also includes a long-term memory . . .," defendants strongly dispute the mischaracterization that the specification talks about "storing data for an extended period." It does not. Instead, the focus in the specification is on the quantity of data, measured in hours, that the long-term memory can hold. The cited sentence states: "The monitor device of the present invention also includes a separate long-term memory for storing more data, hours before and/or after the trigger event, e.g., 12-24 hours or more of additional data, which can also be downloaded." Col. 2, lines 31-34.

5. Long-term storage is a medium for storing data for an extended period, such as solid state memory or a magnetic tape or disk. *(Id.,* col. 3, 11. 19-20.)

Response: Defendants dispute this statement. Nowhere in the citation is there support for the proposition that the long-term memory means "storing data for an extended period." Col. 3, lines 19-23, state "The long-term memory may be either solid state memory or a magnetic tape or disk, etc., recorder. Preferably, the long-term memory is solid state memory sufficient to hold at least 12 hours of ECG data, more preferably at least 24 hours. In numerous places the specifications are to the length of the memory being determined by the number of hours of data that the memory was capable of holding. *See, e.g.*, Abstract;Col. 2, lines 31-34; Col. 4, lines 44-47.

6. As explained in the '143 Patent, "The invention has been described with respect to preferred embodiments. However, as those skilled in the art will recognize, modifications and variations in the specific details which have been described and illustrated may be resorted to without departing from the spirit and scope of the invention as defined in the appended claims." *(Id.,* col. 5,11. 13-18.)

Response: Defendants do not dispute this paragraph.

7. Defendants Braemar and eCardio stand accused of infringing independent claim 18 and dependent claims 19-20 of the '143 Patent. (Oczek Decl., Ex. B.)

Response: Defendants do not dispute this paragraph.

8. Claim 18 of the '143 Patent is set forth below:

> A portable electrocardiographic monitoring device, for attachment to a patient, comprising:
>
> an electrical circuit means for outputting a signal representative of heart rhythms of the patient;
>
> an evaluation buffer means for storing the signal output from said electrical circuit means, and for continuously overwriting the earliest stored signals after its storage capacity is reached, said storage capacity being predetermined;
>
> a holding buffer means for receiving and storing data transferred tom said evaluation buffer means, said evaluation buffer means transferring its stored data to said holding buffer means after receiving an activation signal;
>
> a signal processing means for evaluating the signals representing the heart rhythms of the patient, said signal processing means stores certain parameters therein, compares said signals representing the heart rhythms with said stored parameters and, based on results of said comparison, outputs said activation signal;
>
> a long term storage means for storing signals representative of the heart rhythms of the patient, said long term storage means having a storage capacity greater than that of said evaluation buffer.

(Oczek Decl., Ex. A, col. 6, 11. 35-60.)

Response: Defendants acknowledge that the quotation referenced has been quoted accurately.

9. The '143 Patent states:

> The invention has been described with respect to preferred embodiments. However, as those skilled in the art will recognize, modifications and variations in the specific details which have been described and illustrated may be resorted to without departing from the spirit and scope of the invention as defined in the appended claims.

(Oczek Decl., Ex. A, col. 5, 11. 6-11.)

Response: Defendants acknowledge that the quotation referenced has been quoted accurately.

The ER920W Accused Products

10. In its summary judgment memorandum, Defendants admit that the ER920W Products have an "evaluation buffer" and a "holding buffer" as required by asserted claim 18. Defendants state: "Of the three memories required by the Asserted Claims, the ER920W has an evaluation buffer, and it has a holding buffer that receives signals from the evaluation buffer, but it does not have the required long term storage means [under Defendants' special, narrow definition]." (Defendants' Summary Judgment Motion, Docket No. 65.1, p. 9.)

Response: Defendants dispute this paragraph. These allegations concern portions of the '143 Patent and the ER920W which are not directly at issue in this motion for summary judgment. The ER920W has an evaluation buffer and a holding buffer, but those buffers do not infringe the sections of the '143 Patent relating to those buffers. Defendants have explained this noninfringement in their Final Noninfringement Contentions served on LifeWatch on July 21, 2010, but those contentions are not at issue in this motion, which is focused on noninfringement of the "long term storage means" limitation.

11. Further, in Defendants' responses to LifeWatch's infringement contentions, Defendants admit that the ER920W Products have "an electrical circuit means" and a "signal processing means" as required by asserted claim 18. (Oczek Decl., Ex. C, Ex. A thereto, p. 1.)

Response: Defendants do not dispute this paragraph.

12. FLASH memory is a medium for storing data for an extended period. (Sacerdoti Decl., ¶ 24.) Defendants admit that the ER920W products contain a FLASH memory that stores

ECG data, and that the FLASH memory is capable of storing such data for an extended period. (Defendants' Summary Judgment Motion, Docket No. 65.1, p. 9.)

Response: Defendants do not dispute this paragraph.

13. The ER920W and eVolution Products are portable electrocardiographic monitoring devices for attachment to a patient. (Oczek Decl., Ex. B, Ex. A, p. 1-2.) Defendants' admit this in their responses to LifeWatch's infringement contentions. (Oczek Decl., Ex. C, Ex. A thereto, p. 1.)

Response: Defendants do not dispute this paragraph.

14. The Accused Products contain an electrical circuit (for example, ECG electrodes and leads) that outputs signals representative of heart rhythms of a patient (ECG data). (Oczek Decl., Ex. B, Ex. A thereto, p. 2-3.) Defendants' admit this in their responses to LifeWatch's infringement contentions. (Oczek Decl., Ex. e, Ex. A thereto, p. 1.)

Response: Defendants do not dispute this paragraph.

15. The Accused Products contain an evaluation buffer (RAM memory in the MCU) that stores signal output from the electrical circuit means (ECG electrodes and leads) and continuously overwrites the earliest stored signals after its storage capacity is reached. (Oczek Decl., Ex. B, Ex. A thereto, p. 3-4.) The ECG data stored in the RAM of the MCU is overwritten after the software analyzes the data. *(Id.)* The evaluation buffer has a predetermined storage capacity. *(Id.)* Defendants' admit this in their summary judgment memorandum. (Docket No. 65 at 9.)

Response: Defendants dispute this paragraph. These allegations concern portions of the '143 Patent and the ER920W which are not directly at issue in this motion for summary judgment. The ER920W has an evaluation buffer and a holding buffer, but those buffers do not infringe the sections of the '143 Patent relating to those buffers.

Defendants have explained this noninfringement in their Final Noninfringement Contentions served on LifeWatch on July 21, 2010, but those contentions are not at issue in motion, which is is focused on noninfringement of the "long term storage means" limitation.

16. The Accused Products contain a holding buffer (SRAM memory) that receives and stores data transferred from the evaluation buffer (RAM memory in the MCU) after an activation signal is received. (Oczek Decl., Ex. B, Ex. A thereto, p. 4-5.) Defendants' admit this in their summary judgment memorandum. (Docket No. 65 at 9.)

Response: Defendants dispute this paragraph. These allegations concern portions of the '143 Patent and the ER920W which are not directly at issue in this motion for summary judgment. The ER920W has an evaluation buffer and a holding buffer, but those buffers do not infringe the sections of the '143 Patent relating to those buffers. Defendants have explained this noninfringement in their Final Noninfringement Contentions served on LifeWatch on July 21, 2010, but those contentions are not at issue in this motion, which is focused on noninfringement of the "long term storage means" limitation.

17. The Accused Products contain signal processing (arrhythmia detector) that evaluates signals representing heart rhythms of a patient (*e.g.,* ECG data and derived information). (Oczek Decl., Ex. B, Ex. A thereto, p. 5-7.) Defendants' admit this in their responses to LifeWatch's infringement contentions. (Oczek Decl., Ex. C, Ex. A thereto, p. 2-3.)

Response: Defendants do not dispute this paragraph.

18. The Accused Products contain a long term storage (FLASH memory) that stores signals representative of heart rhythms (ECG data). (Oczek Decl., Ex. B, Ex. A thereto, p. 7-8.)

The FLASH memory can store data during a power-cycle and later transmit the data after start up. A phone ring sounds once if "[a]n event is already stored in memory at startup[.]" (Oczek Decl., Ex. E, B03368, p. 19.) The data stored in FLASH memory includes additional data both before and after the event. The "pre-event time," the default value for which is 30 seconds, is the "[s]econds of ECG data stored before an event activation time." (Oczek Decl., Ex. E, B03363, p. 10.) The "post-event time," the default value for which is 30 seconds, is the "[s]econds of ECG data stored after event activation time." *(Id.)* Accordingly, the ER920W products meet the "long term storage" limitation as required by the asserted claims. (Sacerdoti Decl., ¶ 24.)

Response: Defendants object to this paragraph as violating Rule 56.1 in that it contains multiple statements of fact rather than a "short paragraph." Without waiving that objection, defendants dispute the first and last sentences of this paragraph, which both contain conclusions of law about the "long term storage" requirement of the '143 Patent. Defendants dispute that the ER920W's FLASH memory is a "long term storage means" as that term is used in the Patent. The Patent specification, includes the following statements that make clear that "long term storage" refers to data storage having the capacity of recording at least twelve hours of ECG data:

- **"The monitor includes a separate long-term memory for storing up to 12-24 hours of data which can also be down loaded." Patent, Abstract;**
- **"The monitor of the present invention also includes a separate long-term memory for storing more data, hours before and/or after the trigger event, e.g., 12-24 hours or more additional data which can also be downloaded." Patent, Col. 2, lines 31-34;**
- **The invention's transtelephonic unit "may also permit the downloading of some or all data from the 12-24 hour long-term memory." Patent, Col. 4, lines 44-47;**

The specification emphasizes the invention's capability of recording continuous ECG data as part of its purpose to combine the benefits of both Holter type and event type cardiac monitors:

- **"[T]his invention relates to a wearable device for the selective and continuous recording of electrocardiographic data." Patent, Col. 1, lines 6-7;**

- **"The present invention is directed to an electrocardiographic monitoring and recording device that includes the continuous long term recording of a Holter device and the selective recording of event type records." Patent, Col. 2, lines 13-16;**

- **"Simultaneously with the selective recording, continuous extended recording occurs, allowing for 24 hours or more of ECG data to be captured for evaluation [of] all or any portion." Patent, Col. 1, lines 13-16;**

- **"The present invention is directed to overcoming the shortcomings of both Holter type and event type cardiac monitors." Col. 2, lines 7-9; *see also* Patent, Background of the Invention, at Col. 1, line 18 – Col. 2, line 39 (describing the invention as an improvement over the prior art, consisting of electrocardiographic monitoring devices that functioned either as Holter type recorders or selective recorders, because the invention could serve as both).**

The ER920W's FLASH memory has a maximum storage capacity of thirty minutes and is able to store data in maximum increments of five minutes. See Pls. Response to Stmt. of Undisputed Facts, ¶¶ 48-49.

19. The 93235-93237 CPT Code series also covers Holter monitoring. (Oczek Decl., Ex. F, p. 26 ("93224-93227, 93230-93233, or 93235-93237 cover Holter monitoring.").) eCardio has used and continues to use the 93236 CPT Code for reimbursement of monitoring for the eVolution products. *(Id.,* Ex. G.)

Response: Defendants dispute the allegations of this paragraph. The Holter monitoring codes on Exhibit A to the Affidavit of Robert Jordan are identified as numbers 93224 and 93230, not 93235-93237. The 93235-93237 codes are for noncontinuous recording and 24 hour monitoring. *Id.*

The Phrase "Long Term Storage" Is Known To A Person of Ordinary Skill In the Art

20. The specification of the '143 Patent states that the term "long term storage" is also referred to as "long term memory or extended memory." (Oczek Decl., Ex. A, col. 3, 11. 3-8 ("a long-term storage means (also referred to as long-term memory or extended memory).").) In

other words, the '143 Patent uses the terms "long term storage" and "long term memory" interchangeably. (Sacerdoti Decl., ¶ 16.) The specification explains that "[t]he long-term memory may be either solid state memory or a magnetic tape or disk, etc. recorder." (Oczek Decl., Ex. A, col. 3, 11. 19-20.) This description of long term memory is consistent with how one skilled in the art would understand "long term storage" as the term is used in the '143 Patent. (Sacerdoti Decl., ¶ 16.)

Response: Defendants object to this paragraph as violating Rule 56.1 in that it contains multiple statements of fact rather than a short paragraph. Without waiving that objection, defendants dispute the last sentence of paragraph 20. See the Declaration of Robert Schwarzberg filed by defendants. Dr. Schwarzberg's Declaration states, among other things, that Dr. Schwarzberg is a Board-certified cardiologist who was the chief medical officer of LifeWatch for many years and has been involved in the design of cardiac monitoring devices. Declaration of Robert Schwarzberg, ¶ 1. He is a person of ordinary skill in the art with respect to the '143 Patent. *Id.*, ¶¶ 1-3 & Ex. A.

Dr. Schwarzberg states in his Declaration that the invention of the '143 Patent was to combine together a cardiac event recorder with a long term memory like that of a Holter monitor which has the capacity to record many hours of continuous electrocardiographic data recorded from the patient's heart rhythms ("ECG data"). *Id.*, ¶ 6. In his review of the '143 Patent, Dr. Schwarzberg notes that the novelty in the '143 invention was combining together in one device the benefits one would gain from an event recorder, with the benefits one gains from having a record of long periods of continuous ECG data from the patient's heart. *Id.*, ¶ 7. In this way, the patient's medical team is alerted to arrhythmias, but can also see what is happening during the intervals between the arrhythmia occurrences. *Id.* According to Dr. Schwarzberg, the "long" in "long term

storage" refers to an amount of data measured by the length of time the data is collected, not how long the data is stored. *Id.*, ¶ 9.

From his review of the '143 Patent, Dr. Schwarzberg concludes that "long term storage" in claim 18 of the '143 Patent refers to the capability of extended memory reflecting longer recordings of continuous ECG data, i.e. storing 12 hours or more of continuous ECG data of the patient. *Id.*, ¶ 11.

21. The term "long term memory," which is synonymous and interchangeable with the term "long term storage," is a common and ordinary term used in the computer science field. (Sacerdoti Decl., ¶ 16-24.) One skilled in the art would understand the term "long term storage" to mean "a medium for storing data for an extended period." *(Id.,* ¶ 17.)

Response: Defendants dispute the first sentence as being not relevant to the issues on this motion. With respect to the second sentence, defendants dispute it, as a person of ordinary skill in the art would understand the term "long term storage" in the '143 Patent to mean storage of 12 hours or more of continuous ECG data. See Response to No. 20, *supra*.

22. The McGraw-Hill Dictionary of Scientific and Technical Terms (6th Ed. 2002) defines "long-term memory" as "the storage of information indefinitely so that it can be used again at a later time." (*Id.,* ¶ 18, Ex. B.) This definition of "long-term memory" is consistent with how one skilled in the art would understand "long term storage" as the term is used in the '143 Patent. *(Id.)*

Response: Defendants dispute the first sentence as being not relevant to the issues on this motion. With respect to the second sentence, defendants dispute it as a person of ordinary skill in the art would understand the term "long term storage" in the '143 Patent

to mean storage of 12 hours or more of continuous ECG data. See Response to No. 20, *supra*.

23. Scragg, W. Greg, Problem solving with computers (1997) ("Problem Solving With Computers") states that "[l]ong-term memory holds information that can be retrieved at a later date." *(Id.,* ¶ 19, Ex. C, p. 42) This description of "long-term memory" is consistent with how one skilled in the art would understand "long term storage" as the term is used in the '143 Patent. *(Id.)*

Response: Defendants dispute the first sentence as being not relevant to the issues on this motion. With respect to the second sentence, defendants dispute it as a person of ordinary skill in the art would understand the term "long term storage" in the '143 Patent to mean storage of 12 hours or more of continuous ECG data. See Response to No. 20, *supra*.

24. Dr. Scragg's textbook further describes common examples of long-term memory:

> The most common long-term memory is a magnetic medium, usually a *disc,* but sometimes *tape* .... The most important feature of magnetic information is that it is (relatively) nonvolatile compared to electronic RAM. When a computer is turned off, the magnetic information continues to exist and can be read at any time in the future by a computer (the same or another).

(Id., ¶ 20, Ex. C, p. 43) (emphasis in original)

Response: Defendants do not dispute that this paragraphs contains a quotation from Dr. Scragg's text book that has been quoted accurately, but do not consider those statements to be relevant to how a person of ordinary skill in the art would understand the term "long term storage" in the '143 Patent. See Response to No. 20, *supra*.

25. Dr. Scragg's textbook also states that all long-term memory is logically equivalent; the popular names often refer to physical attributes of the device. *(Id.,* ¶ 21, Ex. C, p. 44) Long-term memory devices can include removable disks (e.g., floppy disks), nonremovable

disks (e.g., hard disks), and tapes. *(Id.)* This description is consistent with how one skilled in the art would explain long term storage as the term is used in the '143 Patent. *(Id.)*

Response: Defendants dispute the last sentence of this paragraph as a person of ordinary skill in the art would understand the term "long term storage" in the '143 Patent to mean storage of 12 hours or more of continuous ECG data. See Response to No. 20, *supra*.

26. U.S. Patent No. 6,128,520 ("the '520 patent"), entitled "Ambulatory Recorder Having Volatile and Non-Volatile Memories," relates to ambulatory recording for medical and especially diagnostic purposes. (Sacerdoti, ¶ 22, Ex. D, col. 1, 11. 6-8.) The '520 Patent describes "long term memory" as memory in which "data can be recorded and preserved, even if power is lost," meaning that data could be stored for an extended period. *(Id.,* Ex. D, col. 3, 11. 43-45.) This description is consistent with how one skilled in the art would understand long term storage as the term is used in the '143 Patent. *(Id.)*

Response: Defendants dispute these statements. The '520 patent has little relevance to this case as it is extrinsic evidence and relates to all manner of medical memory, and is not specific to ecardiographic data monitoring and recording. See Ex. D, Sacerdoti Dec. =The novelty of the invention of the '520 patent is in its method of capturing volatile memory and transferring it to nonvolatile memory without losing any data and is unrelated to the art of ambulatory cardiac monitoring. *Id.* The description provided is not consistent with how a person skilled in the art would understand long-term storage in the '143 Patent. See Response to No. 20, *supra*.

27. U.S. Patent No. 5,664,182 ("the '182 patent"), entitled "Persistent Storage of Report Objects," relates to generating and storing reports as persistent objects. (Sacerdoti, ¶ 23, Ex. E, col. 1, 11. 18-20.) The '182 Patent relates to generating and storing reports as persistent

objects. *(Id.,* Ex. E, col. 1, 11. 18-23.) The '182 Patent states "the term 'long term memory' refers to a non-volatile storage media" such as "a magnetic hard disk, a floppy disk, a CD ROM, etc.," which are devices that store data for an extended period. *(Id.,* Ex. E, col. 5, 11. 45-46; col. 13, 11. 48-50). This description is consistent with how one skilled in the art would understand long term storage as the term is used in the '143 Patent. *(Id.)*

Response: Defendants dispute these statements. The '182 Patent has nothing to do with patient monitoring but instead involves a method for generating highly-formatted searchable reports. Ex. E, Sacerdoti. Defendants dispute the last sentence of this paragraph as a person of ordinary skill in the art would understand the term "long term storage" in the '143 Patent to mean storage of 12 hours or more of continuous ECG data. See Response to No. 20, *supra*.

28. The Encarta World English Dictionary (1999) defines "long-term" to mean "1. IN FUTURE relating to or affecting a time long into the future ... 4. LONG-LASTING continuing for a long period of time." (Oczek Decl., Ex. I (emphasis removed).)

Response: Defendants acknowledge that these statements accurately quote from dictionaries. Defendants dispute that this quote is relevant to the way that a person of ordinary skill in the art would understand the phrase "long term storage" as used in the '143 Patent. See Response to No. 20, *supra*.

29. The Oxford American Dictionary of Current English (1999) defines "long-term" to mean "occurring in or relating to a long period of time *(long-term plans)."* (Oczek Decl., Ex. J (emphasis in original).)

Response: Defendants acknowledge that these statements accurately quote from dictionaries. Defendants dispute that this quote is relevant to the way that a person of

ordinary skill in the art would understand the phrase "long term storage" as used in the '143 Patent. See Response to No. 20, *supra*.

30. The Merriam- Webster's Collegiate Dictionary (10th Ed. 2002) defines "long-term" to mean "occurring over or involving a relatively long period of time." (Oczek Decl., Ex. K.)

Response: Defendants acknowledge that these statements accurately quote from dictionaries. Defendants dispute that this quote is relevant to the way that a person of ordinary skill in the art would understand the phrase "long term storage" as used in the '143 Patent. See Response to No. 20, *supra*.

31. The American Heritage College Dictionary (4th Ed. 2002) defines "long-term" to mean "Involving, maturing after, or being in effect for a long time: *a long-term investment."* (Oczek Decl., Ex. L (emphasis in original).)

Response: Defendants acknowledge that these statements accurately quote from dictionaries. Defendants dispute that this quote is relevant to the way that a person of ordinary skill in the art would understand the phrase "long term storage" as used in the '143 Patent. See Response to No. 20, *supra*.

Dated: August 10, 2010

DEFENDANTS BRAEMAR, INC. AND ECARDIO DIAGNOSTICS, LLC

/s/ John L. Krenn

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